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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,148	10/31/2003	Jonathan Kagan	VALTX.001A	2819

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
02/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/698,148	KAGAN ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-50,52,54-61,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-50,52,54-61,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's communication of 11/21/2008. Currently elected amended claims 43-50, 52, 54-61 and 72-73 are pending and rejected below.

Response to Arguments

Applicant's arguments, see remarks filed 11/21/2008, with respect to the objection over the term "T-tag" and claim 52 have been fully considered and are persuasive. The objection of claim 52 has been withdrawn.

Applicant's arguments filed 11/21/2008 concerning the 103 rejections below have been fully considered but they are not persuasive. Applicant's argue that a Prima Facie case of obviousness since the spikes have the same configuration when passing through the luminal wall compared with after passing through the luminal wall (see Thompson declaration at para 6). And that this statement in the Thompson Declaration is evidence why the tissue anchors cannot be a tissue anchor "configured to have a transversely reduced configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally through the attachment site... " as in claim 43. Examiner is of the position that the spikes do have "the same configuration when passing through the luminal wall compared with after passing through the luminal wall" and also this configuration would have a transversely reduced configuration for passing transmurally through the attachment site and a transversely enlarged configuration after passing transmurally

through the attachment site. The “configuration” of the device doesn't change rather the anchor has a transversally reduced configuration going in and transversally enlarged configuration going out. Further it has been held that the recitation that an element is “configured for” to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in a patentable sense.

Applicant’s further argue that one of ordinary skill would have no reason to combine and modify the references (applicant's position that Gannoe doesn't intent or disclose there specific attachment). Examiner is of the position that as long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor. Clearly Taylor discloses solving the attachment problem (see rejection below). Evidence of non-obviousness must be given consideration, but does not mandate a conclusion of non-obviousness. While there must be some teaching, reason, suggestion, or motivation that the references be combined to arrive at the claimed invention, there is no requirement that the references explicitly suggest the combination. The suggestion or motivation to combine the rreferences or teaching can derive solely from the existence of a teaching, which one of ordinary skill in the art would be presumed to know, and the use of that skill in the art would be presumed to know, and the use of that teaching to solve the same or similar problem which it addresses.

In this case both Gannoe and Bessler are not used to teach attaching tissue anchors configured to have a transversely reduced configuration for passing

transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface,

The elements and methods disclosed in the prior art of record are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 103 (2nd time)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler (U.S. Application Number 2004/0039452 A1) in view of Taylor (U.S. Patent 6,254,642).

Bessler discloses an endoscopic gastric bypass device and methods (figures 1-4). Bessler discloses a method for treating obesity with the steps of providing a gastric sleeve (figure 4) with a proximal end (42), distal end (44), and lumen extending threrethrough (40), transesophageally advancing the sleeve adjacent an attachment site near the gastroesophageal junction (near 60), advancing the proximal end through the stomach and into the intestines or beyond, and attaching the proximal end at the attachment site to deliver food from the esophagus directly into the intestine (see paragraphs [0012]-[0027]). Bessler discloses a support tissue anchor tubular cuff, at the site of attachment, (42), and extending the sleeve (40) distally of duodenum or beyond (paragraph [0020]. Further Bessler discloses that the length of the tube sleeve could be up to 250cm or beyond in length [0020] and permanently attached to the cuff. The Bessler device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pyloris.

Bessler discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Bessler with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25). Concerning the claim language of “without creating a serosal to serosal bond” it is examiners

position that the type of attachment depicted in figures 6a-6e would not create a serosal to serosal bond.

Claims 43-50, 52, 54-61 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gannoe et al. (U.S. Application Number 2004/0082963 A1) in view of Taylor (U.S. Patent 6,254,642).

Gannoe discloses a method and device for use in endoscopic organ procedures. Gannoe discloses a method for treating obesity and providing a lengthy sleeve and support tissue anchor with a temp or permanent cuff by suture transesophageally to an attachment site near the gastroesophageal junction, with a proximal and distal ends, where the distal end can extend into the intestines or beyond (See paragraph [0035]). The attachment site support may be implanted with or without the sleeve (see figure 5A-5E, specifically 5E). The Gannoe device is fully capable of being sufficiently flexible that the material traveling through the sleeve is influenced by the natural operation of the pyloris.

Gannoe discloses the claimed invention except for the attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site, and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface. Taylor teaches that it is known to use attaching tissue anchors configured to have a transversely reduced configuration for passing transmurally through the attachment site,

and a transversely enlarged configuration after passing transmurally through the attachment site wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface, (as set forth in paragraphs at columns 7-9, and shown in figures 6a-6E) to provide an efficient low profile anchoring system with a size that resists cutting or tearing of tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Gannoe with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface as taught by Taylor, since such a modification would provide the method with a transversally reduced/enlarged configured tissue anchors wherein the distal end of the tissue anchor includes a proximally facing surface which rests against a serosal surface for providing an efficient low profile anchoring system with a size that resists cutting or tearing of tissue (column 11 lines 14-25).

Claims 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler in view of Taylor or Gannoe in view of Taylor. Both references disclose the method claimed except for the specifics of the tissue anchor. Both Bessler in view of Taylor or Gannoe in view of Taylor discloses the claimed invention except for transmurally implanting a “T-tag” to attach the cuff. It would have been obvious to one having ordinary skill in the art at the time the invention was made to transmurally implanting a “T-tag” to attach a cuff, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the

intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).* The use of the "T-tag" is simply a preferred type of fastener, Gannoe specifically teaches using staples or sutures to attach to a site. It would have been obvious to use a "T-tag" as a preferred type of fastener to securely attach the cuff to the site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767